DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 8,2015

Anutra Medical Inc.
c/o Cameron Perkins
1000 Perimeter Pike, Suite E
Morrisville, NC 27560

Re: K143757
Trade/Device Name: Anutra Feedback Aspiration Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Product Code: FMF
Regulatory Class: II
Dated: December 18, 2014
Received: December 31, 2014

Dear Cameron Perkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143757

Device Name
ANUTRA Feedback Aspiration Syringe

Indications for Use *(Describe)*
The ANUTRA Feedback Aspiration Syringe is intended for use by healthcare professionals for general purpose fluid aspiration/injection.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5.0 510(k) Summary K143757

5.1. Submitter Information

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Date Summary Prepared: December 18, 2014

5.2. Device Identification

Trade/Proprietary Name: ANUTRA Feedback Aspiration Syringe

Common Name: Control Syringe

Classification Name: Piston Syringe
21CFR 880.5860, Class II

Classification Panel General Hospital

Product Code: FMF (Syringe, piston)

5.3. Predicate Device

The ANUTRA Feedback Aspiration Syringe is substantially equivalent to the following predicate device:

Device	Manufacturer	510(k)	Date Cleared
BD Single Use, Hypodermic Syringe	Becton, Dickinson and Company	K110771	May 13, 2011

5.4. Device Description

The ANUTRA Feedback Aspiration Syringe is a piston syringe (control syringe) consisting of a plastic barrel which contains a printed graduated scale (5mL nominal volume) and 6% male Luer Lock connection, a plunger, and a plastic plunger rod. The internal surface of the ANUTRA Feedback Aspiration Syringe barrel is lubricated with polydimethylsiloxane (silicone). The plunger rod design contains a finger ring to allow for ease of use, and tab features with interface with the barrel to provide audible and tactile feedback to the user.

The ANUTRA Feedback Aspiration Syringe is single-use only, non-pyrogenic, and sterilized by gamma irradiation.

5.5. Intended Use

The ANUTRA Feedback Aspiration Syringe is intended for use by healthcare professionals for general purpose fluid aspiration/injection.

5.6. Predicate Device Comparison – Technical Characteristics

Equivalency of technical characteristics is demonstrated through a direct comparison of the ANUTRA Feedback Aspiration Syringe and the predicate device listed in the table below.

Technical Characteristic	Subject Device: ANUTRA Feedback Aspiration Syringe	Predicate Device: BD Single Use, Hypodermic Syringe (K110771)
Barrel	Yes	Yes
Plunger Rod	Yes	Yes
Plunger	Yes	Yes
Luer Configuration	Luer Lock	1mL – Luer Slip 3mL and 5mL – Luer Lock
Nominal Fluid Volume	5mL	1mL, 3mL and 5mL
Lubrication	Polydimethylsiloxane (silicone)	Unknown, device assumed to be lubricated
Sterilization Method	Gamma irradiation	Ethylene oxide or gamma irradiation

The predicate device is a piston syringe. The ANUTRA Feedback Aspiration Syringe is a type of piston syringe (specifically, a control syringe). The intended use for the ANUTRA Feedback Aspiration Syringe is the same as its predicate device, the BD Single Use, Hypodermic Syringe (K110771).

Barrel

The volume of fluid contained within the both the ANUTRA Feedback Aspiration Syringe and the predicate device is indicated by graduation marks printed on the outside of the barrel. The ANUTRA Feedback Aspiration Syringe has a plastic barrel with a 5mL nominal fluid volume. A 5mL variant of the predicate device contains the same nominal volume.

Luer Configuration

Both the subject device and the predicate device are offered in a male Luer Lock configuration. The predicate device is also available in a Slip Luer configuration (1mL only).

Nominal Fluid Volume

The nominal fluid volume for both the subject device and the predicate device is 5mL. The predicate device is also available in other fluid volumes.

Lubrication

The internal surface of the ANUTRA Feedback Aspiration Syringe is coated with a polydimethylsiloxane (silicone). The predicate device 510(k) summary does not specify whether or not the predicate device is lubricated, however based on an inspection of the predicate device, it is believed to be lubricated.

Plunger Rod & Plunger

Both the subject device and the predicate device have a plastic plunger rod and a synthetic rubber plunger; the plunger is attached to the plunger rod with snap-fit retention features. The ANUTRA Feedback Aspiration Syringe plunger rod contains features which provide audible and tactile feedback when the plunger is advanced or retracted, and a finger ring for ease of use and handling the device. The predicate device has a flat push-button on the end of its plunger rod. The mechanism for delivery of fluid is the same for both the subject device and predicate devices.

Sterilization Method

The ANUTRA Feedback Aspiration Syringe is sterilized using gamma irradiation. The predicate device can be sterilized by either gamma irradiation or ethylene oxide.

Materials

The ANUTRA Feedback Aspiration Syringe is constructed of the following polymeric components:

- Barrel: Polypropylene copolymer
- Plunger Rod: Polypropylene copolymer
- Plunger: Synthetic (polyisoprene) rubber
- Lubrication: Polydimethylsiloxane (silicone)

The subject device has been tested and meets the biological requirements outlined in ISO 10993-1. A summary of these test results is provided in Section 15 – Biocompatibility.

5.7. Predicate Device Comparison – Performance Characteristics

The performance data supplied with this submission demonstrates that the ANUTRA Feedback Aspiration Syringe meets the specified requirements and is substantially equivalent to the predicate device.

The predicate device (BD Single Use, Hypodermic Syringe) provided an overview of testing completed in the 510(k) Summary (K110771). These tests were used to compare the subject device and the predicate device performance.

Tests Performed on Subject Device and Predicate Device (as indicated in the predicate device 510(k) Summary):

- ISO 7886-1
  - Section 6 (Limits for Acidity or Alkalinity)
  - Section 7 (Limits for Extractable Metals)
  - Annex D Liquid leakage at syringe piston under compression
  - Annex G Forces to operate the plunger

Tests Performed on Subject Device:

- ISO 7886-1
  - Section 5 (Cleanliness)
  - Section 8 (Lubricant)
  - Section 9 (Tolerance on graduated capacity)
  - Section 10 (Graduated Scale)
  - Section 11 (Barrel)
  - Section 12 (Piston/plunger assembly); Annex B
  - Section 13 (Nozzle)
  - Section 14.1 (Dead Space)
  - Section 14.2 (Freedom from air and liquid leakage past piston); Annex B and Annex D
  - Section 15 (Packaging)
  - Section 16 (Labeling)

- ISO 594-2
  - Section 3 (Dimensions and tolerances)
  - Section 4.1 (Gauging)
  - Section 5.2 (Liquid leakage from fitting assembly under pressure)
  - Section 5.3 (Air leakage into fitting assembly during aspiration)
  - Section 5.4 (Separation force of fitting assembly)
  - Section 5.5 (Unscrewing torque of fitting assembly)
  - Section 5.6 (Ease of assembly)
  - Section 5.7 (Resistance to overriding)
  - Section 5.8 (Stress cracking)

- Sterile Barrier Packaging Testing
  - ASTM F2096 – 11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
  - ASTM F88-09 Standard Test Method for Seal Strength of Flexible Barrier Materials
  - ASTM F1886 / F1886M - 09(2013) Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

- General performance
  - Syringe package shall be easy to open with gloved hands
  - Syringe shall be able to aspirate and deliver using one hand
  - Tactile feedback
  - Finger reach

- Biocompatibility Testing (ISO 10993)
  - Cytotoxicity by Elution Test (Cytotoxicity)
  - Intracutaneous Reactivity (Irritation or Intracutaneous Reactivity)
  - Maximization Test for Delayed Hypersensivity (Sensitization)
  - Acute Systemic Toxicity (Systemic Toxicity (Acute))
  - Evaluation of Hemocompatibility: Interaction with Blood (Hemocompatibility/Hemolysis)

5.8. Conclusion

Test results demonstrated that the ANUTRA Feedback Aspiration Syringe is as safe, as effective and performs as well as or better than the legally marketed predicate device (BD Single Use, Hypodermic Syringe).

Based on comparisons of the device's intended use, technology and performance characteristics, the ANUTRA Feedback Aspiration Syringe is substantially equivalent to the indicated predicate device. Any differences between the ANUTRA Feedback Aspiration Syringe and the predicate device have no significant influence on safety or effectiveness.